K001484

JUN 1 9 2000

510(k) Summary
for ALKO Reagents on
ABL™ 5
pH/ Blood Gas Analyzer

The products encompassed by this 510(k) submission are Class II (75JIX) In Vitro Diagnostic Solutions manufactured by ALKO Diagnostic Corporation, 333 Fiske Street, Holliston, MA 01746. The Reagents are intended for use on equivalent ABL™ 5 pH/ Blood Gas Analyzer. Radiometer Medical/Copenhagen is the original equipment manufacturer (OEM) of the analyzers and of predicate reagents which are necessary for the continued operation and use of the analyzer.

Information herein will support ALKO's position for the intended use of these products to the equivalent ABL™ 5 pH/ Blood Gas Analyzer. The ABL™ 5 pH/Blood Gas Analyzer perform blood gas tests. ALKO manufactures the calibration reagents for the analyzer's analyte pH (concentration of hydrogen ions) which is measured by the glass membrane electrode. ALKO also manufactures the Rinse Solution. The ALKO Reagents are intended to be used with equivalent ABL™ 5 pH/Blood Gas Analyzer. As such, ALKO products are intended for use in place of like named products manufactured by Radiometer Medical/Copenhagen.

The Calibration Solution, pH 7.383/**1** and Calibration Solution, pH 6.841/**2** are buffered solutions for calibration of the pH electrode. The Rinse Solution **/R** is used to clean and rinse the analyzers electrodes, and sample flow path.

- ALKO product A943-837 (Calibration Solution **1**, pH 7.383) is equivalent to Radiometer Medical/Copenhagen product S1545 / 943-837 (Calibration Solution 1, pH 7.383).
- ALKO Product A943-839 (Calibration Solution **2**, pH 6.841), is equivalent to Radiometer Medical/Copenhagen S1555 / 943-839 (Calibration Solution 2, pH 6.841).
- ALKO product A943-838 (Rinse Solution, **R**) is equivalent to Radiometer Medical/Copenhagen product S4911 / 943-838 (Rinse Solution).

ALKO uses a similar composition, description and packaging design as that used by Radiometer Medical/Copenhagen in its products. Equivalence is explained in the packaging section of this submission. ALKO has shown performance equivalence of its products to Radiometer Medical/Copenhagen products in the following manner:

- Through a method comparison where results obtained on an equivalent ABL™ 5 pH/Blood Gas Analyzer, calibrated with ALKO products and compared with results obtained on the same type of analyzer calibrated with Radiometer Medical/Copenhagen products; and

- Through a precision study where ALKO products were installed on an equivalent ABL™ 5 pH/ Blood Gas Analyzer and three levels of controls were measured on pH/pCO_2/pO_2 per day for over a twenty-day period. A summary of the results of these studies follows:

PERFORMANCE CHARACTERISTICS

Precision Data

Precision data were collected from the analyses of three levels of control materials measured twice per run for over a twenty-day period on an ABL™ 5 pH/pCO2/pO2 analyzer calibrated with all ALKO reagents.

pH

Level		N	Mean	STD	CV%
Level 1	Total	60	7.15	0.0022	0.0307
	W-Run	30	7.15	0.0013	0.0181
Level 2	Total	60	7.40	0.0018	0.0245
	W-Run	30	7.40	0.0018	0.0247
Level 3	Total	60	7.61	0.0041	0.0545
	W-Run	30	7.61	0.0013	0.0170

pCO_2

Level		N	Mean	STD	CV%
Level 1	Total	60	75	1.6919	2.2462
	W-Run	30	75	1.7176	2.2794
Level 2	Total	60	43	0.8150	1.8841
	W-Run	30	43	0.6708	1.5510
Level 3	Total	60	20	0.3339	1.6764
	W-Run	30	20	0.3416	1.7150

pO_2

Analyte		N	Mean	STD	CV%
Level 1	Total	60	59	1.5378	2.6223
	W-Run	30	59	1.4201	2.4213
Level 2	Total	60	102	1.4578	1.4278
	W-Run	30	102	1.2715	1.2451
Level 3	Total	60	158	2.2714	1.4338
	W-Run	30	158	1.7416	1.0995

Note: W-Run = Within Run

Accuracy by Correlation with Radiometer ABL™ Reagents

Correlation data were obtained from 76 human whole blood samples and control materials for pH/pCO2/pO2, measured on two ABL™ 5 analyzers, one calibrated with all ALKO reagents as compared with the other one calibrated with all Radiometer reagents. A Linear Regression Analysis was performed using the Radiometer data as the Independent X Variable and ALKO Data as the Dependent Y Variable in the equation Y = a + bX.

Analyte	N	Slope	Intercept	R Squared *	Range
PH	85	0.9814	0.1332	0.9994	6.58 - 7.96
pCO2	85	1.0163	0.5559	0.9973	1- 136
pO_2	85	0.9939	0.4684	0.9990	15 - 267

*R Squared= Correlation Coefficient Squared

I hope you find this information useful and informative.

4/28/00
(date prepared)

Patrick Chiu
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 9 2000

Mr. Patrick Chiu
Quality Assurance Manager
Alko Diagnostic Corporation
333 Fiske Street
Holliston, Massachusetts 01746

Re: K001484
Trade Name: Calibration Solution 1, Calibration Solution 2 and Rinse Solution Kit for use on Equvalent ABL™ 5 pH/Blood Gas Analyzer
Regulatory Class: II
Product Code: JIX
Dated: April 28, 2000
Received: May 11, 2000

Dear Mr. Chiu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001484

Device Name: Calibration Solution 1, Calibration Solution 2 and Rinse Solution Kit for use on Equivalent ABL™ 5 pH/Blood Gas Analyzer

Indication For Use:

The products encompassed by this request are intended for in vitro diagnostic use and are intended for use in calibrating the electrodes and cleaning / flushing the sample flow path of the equivalent ABL™ 5 pH/Blood Analyzer. Radiometer Medical/Copenhagen is the Original Equipment Manufacturer of the analyzer and of the predicate Reagents. The ABL™ 5 pH/Blood Gas Analyzer performs a broad array of blood gas tests. ALKO manufactures the calibration reagents for the analyzer's analyte pH, (concentration of hydrogen ions) which is measured by glass membrane electrodes. ALKO also manufactures the Rinse Solution. This Reagent is intended to be used with the equivalent ABL™ 5 pH/Blood Gas Analyzer. As such, ALKO products are intended for use in place of like named products manufactured by Radiometer Medical/Copenhagen.

The Calibration Solution, pH 7.383/ **1** and Calibration Solution, pH 6.841/ **2** are intended to provide calibration points for the pH electrode on the analyzer. The Rinse Solution /**R** is intended for maintenance of the analyzers electrodes and sample flow path. The products encompassed are to be handled using normal laboratory precautions.

Sean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001484

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)